Ramon Rossi Lopez - rlopez@lopezmchugh.com
(California Bar Number 86361; admitted *pro hac vice*)
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Mark S. O'Connor (011029) – mark.oconnor@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Co-Lead/Liaison Counsel for Plaintiffs

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation LISA HYDE and MARK HYDE, a married couple, Plaintiffs, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	No. MD-15-02641-PHX-DGC **PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* NO. 1 TO EXCLUDE EVIDENCE OF RECOVERY FILTER CEPHALAD MIGRATION DEATHS** (Assigned to the Honorable David G. Campbell) (Oral Argument Requested)

Plaintiffs oppose Defendants' C.R. Bard, Inc. and Bard Peripheral Vascular Inc., (collectively "Bard") Motion *in Limine* No.1 to exclude evidence of Recovery Filter Cephalad Migration Deaths.

ARGUMENT AND CITATION OF AUTHORITY

I. Deaths Associated With The Recovery Filter Are Relevant Because They Were The Basis for The G2 Filter's Design And Evidence Of The Feasibility Regarding Creation of A Safer Alternative Designs.

There is no dispute that the G2X[1] Filter Plaintiff Lisa Hyde received is the *same filter* as the G2 Filter cleared by FDA using Bard's Recovery Filter as a predicate; Bard has admitted this in previous assertions to this Court, it has been declared by its lead engineer and supported by Bard internal documents. Excluding evidence of the deaths associated with the predicate Recovery Filter that led to the G2's design would be unduly prejudicial to Mrs. Hyde in proving a design defect case. Such a ruling would exclude the complete history of the G2X filter's design and why it exists causing the jury to deliberate without the complete G2 design story. This Court has ruled that evidence that prompted the creation and design of the G2 is information relevant to a design defect claim involving the G2 Filter. (Doc. 10323, at 4). Moreover, as seen in the previous two bellwether trials, Bard relies heavily on FDA-related evidence to justify its design as somehow FDA-authorized or accepted with the clearance of its filters and with FDA communications. Bard fought vigorously to keep its IVC filters' regulatory history relevant and admissible in these trials.

[1] There is a dispute between the parties as to which filter Mrs. Hyde received. This Court ruled that the issues of product identification is for the jury. (Doc.12157). Mrs. Hyde claims that her filter was a G2X Filter and asserts she should be permitted to put on unredacted evidence relevant to a G2 Filter

(Doc. 9690). To exclude the reasons for seeking FDA clearance of the G2 Filter[2] (the Recovery Filter's deaths) would give Bard an unfair advantage to present its case as if there were no serious design problems originating in the filter it claims was a mere modification of the Recovery Filter and the reasons why the design was modified in the first place.

A. The G2 Filter Mrs. Hyde Received is the Same Filter Predicated on the Recovery.

The G2 Express/G2X Filter System is comprised of the same G2 Filter predicated on Bard's Recovery Filter and therefore relevant to this case. Fed. R. Evid. 401, 402. *See*, Ex. A to Doc. 5398, Declaration of Robert Carr, at ¶105 (discussing the G2 Express/G2X Filter System 510(k) application). Robert Carr is familiar to the Court at this juncture having appeared at trial in *Booker* and *Jones* and having signed a 58-page declaration in March of 2017 including documents related to FDA submissions regarding most of Bard's permanent filters with optional retrievability. Bard declared to the FDA that with the Recovery as the predicate device, G2's "design, material, components, fundamental technology (mode of device, function/operation) and intended use featured" was "substantially equivalent to those [features] with the predecessor Recovery Filter System…". (Doc. 1006-1 at 25). Bard argues that the 510(k) regulatory process is a design process, insinuating that it evaluates the design of a product. Exhibit A, *Booker* Trial, Bard Opening Statement Slide 65. When its first recoverable IVC filter (i.e., Recovery) began experiencing reports of death, Bard took regulatory action in the form of seeking clearance of what it called an improved design

[2] The G2 Express/G2X Filter System is comprised of the same G2 Filter predicated on the Recovery Filter. *See*, Exhibit A to Doc. 5398, Affidavit of Robert Carr, at ¶105 discussing the G2 Express/G2X Filter System 510(k) application: "Using the recently cleared G2 Filter System for removal indication (K073090) as a predicate device…[o]other than the addition of the tip, no other changes to the filter were made."

known as the G2 Filter and represented its purpose to FDA as: "to introduce a modified Recovery Filter System..." Exhibit B, at BPV-17-01-00125355. Bard has also affirmatively stated that "one of Bard's goals in developing the G2 Filter and seeking FDA clearance was to reduce the number of incidents of filter fracture and migration that Bard had observed with the Recovery Filter." Doc. 9862 at 4.

Moreover, Mr. Carr represented to this Court in his March 2017 declaration[3] that there were no changes to the filter itself between the first G2 Filter's 510(k) application the G2X Mrs. Hyde received; there was only a hook added to the top for retrievability:

Regarding the G2 Filter:
Para. 47. "On March 2, 2005, BPV submitted a Special 510(k) application for a modified Recovery Filter (to be called the G2 Filter). The application, made significant dimensional modifications to the predicate device, the Recovery Filter, but incorporated no material changes or additional components."

Regarding the Recovery G2 Filter – G2 Filter System For Removable Indication:
Para. 103. "On October 31, 2007, BPV submitted its over 1500-page traditional 510(k) for the G2 Filter System…seeking to remove the limitation on its previous 510(k) clearance for the device and obtain clearance for removable indication."

Regarding the G2 Express Filter System:
Para. 105: "On March 7, 2008, BPV submitted a Special 510(k) for its G2 Express Filter system…Using the recently cleared G2 Filter System for removal indication as a predicate device, BPV sought to gain approval[4] for filter with an electropolished snarable tip. Other than the tip, no other changes to the filter were made."

Regarding the G2X Filter:
Para. 114: "On August 12, 20008, BPV submitted a Special 510(k) for its G2 Express Filter system…(subsequently known as G2X), which included to the delivery system only. In this submission, the filter remained unchanged…"

[3] Mr. Carr's Declaration can be found as Exhibit A to Doc. 5398.
[4] The word "approval" is a direct quote from the declaration and not utilized by Plaintiffs as such a representation presumably is in violation of 21 C.F.R. 807.97.

With these admissions, despite any product identification issue for this trial, the G2 Filter that is part of the G2X Filter system is the same G2 Filter subject to this Court's previous ruling on the relevance of the Recovery Filter's complications. When Mrs. Hyde received her filter is not relevant to determining whether this evidence is admissible; the filter is the filter. If Bard is permitted to put forth evidence that the 510(k) process is a design process and that Bard worked with FDA hand-in-hand as a collaborator in the design process, then Mrs. Hyde should be permitted to tell the entire story about the design changes to the G2 Filter including the reasons why the Recovery's design was modified. Fed. R. Evid. 403. Bard's approach is an "all or nothing" tactic that would result in excluding the allegedly offensive evidence for allegedly prejudicial reasons and shifting the alleged unduly prejudicial effect onto the Plaintiffs who would be bereft of the ability to tell the whole story. As such, Plaintiffs are respectful of and informed by this Court's previous rulings on the cephalad migration issue. Plaintiffs have a history of following those rulings conscientiously when including evidence of cephalad migration deaths. Exhibit C, *Booker* Trial Tr. 3/14/18 at 16:6-18:15 (providing explanation that inclusion of deaths associated with the Recovery Filter during opening statements was to lay the foundation for the QA hold which gives context for the re-design of the Recovery resulting in the G2 Filter's existence.) Plaintiffs have no intention of over-emphasizing the history of deaths associated with the Recovery Filter as they relate to the design of the G2 Filter and respectfully request this Court enter an Order similar to its March 2, 2018 ruling on the matter. *See*, Doc. 10323, at 4. Plaintiffs have not and will not run afoul of this Court's March 2, 2018 ruling and will avoid heavy emphasis of Recovery-related deaths with the exception of the context the

events would give to the design of the G2 Filter and the relevance of such evidence to proving a design defect under Wisconsin law discussed in more detail, *infra*.

B. The Reasons for the Design Changes to the Recovery Filter is Relevant to Plaintiffs' Design Defect and Punitive Damage Claims Under Wisconsin Law.

Under Wisconsin law, Plaintiffs must show that "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. §895.047; WIS JI-CIVIL 3260.1. Evidence of Bard's ability to modify a design in the face of a safety issue as it did with the Recovery Filter is particularly relevant now, since in previous trials Bard's witnesses have testified that changes to its filters were not effectuated quickly including changes that could have made Mrs. Hyde's G2 device safer.[5] Yet Bard, in the face of deaths associated with its Recovery Filter. was able to sit down and begin its redesign within nine months of the Recovery Filter reaching the market and two days after the report of a second death. This evidence is crucial to Plaintiffs' case as Bard's abilities, i.e., the feasibility aspect, to design a safer alternative design could be outcome determinative in a state like Wisconsin. *Below v. Yokohama Tire Corp.*, 2017 WL 679153, at *3 (W.D. Wis. Feb. 21, 2017) (discussing feasibility evidence in a design defect case applying Wisconsin law). Bard efficiently sought to modif its Recovery device to reduce cephalad migration deaths in the face of a public crisis. Now it seeks to distance itself from the ability to make immediate changes

[5] Ex. D, Testimony of Michael Randall, *Jones* Trial Tr., at 2231:7-12; Ex. E, Testimony of Bret Baird, *Jones* Trial Tr., at 877:9- 25.

where the type of migration at issue was silent in the public due to what Bard claims are asymptomatic events. Mrs. Hyde was injured by a lack of adequate design and re-design. The evidence Bard seeks to exclude supports Mrs. Hyde's claim for defective design and her punitive damage claim and sum[6]. WIS JI-CIVIL 1707.2. For the above stated reasons, Plaintiffs respectfully request this Court deny Bard's *Motion in Limine* No.1 To Exclude Evidence Of Recovery Filter Cephalad Migration Deaths.

RESPECTFULLY SUBMITTED this 28th day of August 2018.

GALLAGHER & KENNEDY, P.A.

By:*/s/ Mark S. O'Connor*
Mark S. O'Connor
2575 East Camelback Road
Phoenix, Arizona 85016-9225

LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of August 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Jessica Gallentine

[6] Evidence of Bard's ability to triage safety issues as they did with the Recovery deaths is relevant to whether Bard acted with an intentional disregard of Mrs. Hyde's rights in that it shows what Bard was capable of doing with haste in a previous situation. It also supports that Bard was aware that its acts (or lack thereof) were substantially certain to result in Mrs. Hyde's rights being disregarded. It also supports goes to the factors used to determine a sum for punitive damages, such as attitude and conduct. *See,* WIS JI-CIVIL 1707.2.